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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/893,759	07/11/1997	KAZUNORI SAITOH	1587-0024-0	8270

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EXAMINER	
CHIN, CHRISTOPHER L	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 07/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
08/893,759	Saitoh et al
Examiner	**Art Unit**
Chris L. Chin	1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *1/16/03 and 4/16/03*

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *7-42* is/are pending in the application.

4a) Of the above, claim(s) *17, 31, 36-38, and 40-42* is/are withdrawn from consideratio

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *7-16, 18-30, 32-35, and 39* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examine

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 U.S.C. § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 7, 10-13, and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strahilevitz (US Patent 4,375,414) in view of Schmidtberger (US Patent 5,180,679) or Young et al (US Patent 5,460,947) for the reasons of record.

In response to this rejection, Applicants argue that Strahilevitz is only directed to detection of psychoactive drugs and thus fails to describe detection of apoprotein B, HbA_1C, serum amyloid A protein, or thrombin-antithrombin III complex. Applicants also argue that Schmidtberger and Young et al are only directed to detection of apoprotein B and not to detection of psychoactive drugs. Applicants also argue that the Examiner has not provided any explanation as to why one would be motivated to combine these three references.

Applicant's arguments have been considered but are not convincing. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references.

See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). If Strahilevitz taught detection of apoprotein B, HbA_1C, serum amyloid A protein, or thrombin-antithrombin III complex, then the reference would have been applied as a 102 reference. Applicants arguments are not addressing the combined teachings of Strahilevitz, Schmidtberger, and Young et al. It should also be noted that Strahilevitz is not limited to just the detection of psychoactive drugs. Such detection is merely a preferred embodiment of the agglutination assay disclosed in Strahilevitz. Applicant's attention is directed to column 2, lines 60-63, of Strahilevitz which states "The invention also encompasses the determination of haptens, and particularly psychoactive haptens, by simple and accurate agglutination and agglutination-inhibition assays." which clearly states that determination of haptens in general is contemplated and psychoactive drugs are merely a preferred analyte to be detected. Motivation to combine the references was set forth in the rejection in the previous office action.

3. Claims 21-27, 29, 30, and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer Mannheim GMBH (EP 617 285 A2) in view of Schmidtberger (US Patent 5,180,679) or Young et al (US Patent 5,460,947) for the reasons of record.

In response to this rejection Applicants argue that the Examiner has failed to provide any evidence to demonstrate that one skilled in the art would have a reasonable expectation that the

antibodies in Schmidtberger or Young et al would actually work in the assay of EP '285 and reduce the Hook effect.

Applicant's arguments have been considered but are not convincing. Page 3 of EP '285 requires a carrier bound antibody and soluble antibody to carry out the disclosed assay. Apparently, that is all that is necessary to reduce the Hook effect. The soluble antibody referred to as R_2 reduces or completely avoids the Hook effect. There is no special requirement of the soluble antibody except that it be an antibody. Thus, one of ordinary skill in the art would have a reasonable expectation of success in using the antibodies of either Schmidtberger or Young et al in the assay of EP '285.

4. Claims 7-16, 18-30, 32-35, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cragle et al (WO 85/02258) in view of Strahilevitz (US Patent 4,375,414), Boehringer Mannheim GMBH (EP 617 285 A2), Schmidtberger (US Patent 5,180,679) and Young et al (US Patent 5,460,947) for the reasons of record.

In response to this rejection Applicants argue that no motivation to combine the reference has been set forth by the Examiner.

Applicant's argument has been considered but is not convincing because contrary to Applicant's argument, motivation for combining the references was set forth in the rejection in the previous office action.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Chin whose telephone number is (703) 308-3991. The examiner can normally be reached on Monday-Thursday from 10:00 am to 7:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Christopher L. Chin

cchin/cc
June 30, 2003

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641